DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

NOV 1 5 2001

DADE BEHRING

K011852

Summary of Safety and Effectiveness Information

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 607.92

Submitter's Name: Cathy P. Craft
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Date of Preparation: June 8, 2001

Device Name: Dimension® HA1C Assay

Classification Name: Glycosylated Hemoglobin

Predicate Device: Roche Tina-quant® HBA1C II

Device Description: The Dimension® HA1C assay measures both HbA1c and hemoglobin. The HbA1c measurement is based on a turbidimetric inhibition immunoassay (TINIA) principle, and the measurement of total hemoglobin is based on a modification of the alkaline hematin reaction. Using the values obtained for each of these two analytes (in g/dL), the percentage of the total hemoglobin that is glycated is calculated and reported as %HbA1c. The final %HbA1c result has been standardized to the results obtained in the Diabetes Control and Complications Trial (DCCT).

Pre-treatment to remove the labile fraction is not necessary as only the Amadori rearranged form of HbA1c is detected. All hemoglobin variants that are glycated at the beta-chain N-terminus and have epitopes identical to that of HbA1c, are measured by this assay.

Principles of Procedure:

Total Hemoglobin Measurement: A sample of whole blood is added to the first cuvette containing lysing reagent. This reagent lyses the red blood cells and simultaneously converts the released hemoglobin to a derivative that has a characteristic absorbance spectrum. An aliquot of the lysed whole blood is transferred from the first cuvette to a second cuvette where total hemoglobin concentration is measured at 405 nm and 700 nm.

Whole blood + lysing agent -→ Released hemoglobin → hemoglobin derivative (measured at 405 nm)

Hemoglobin A1c Measurement: The same aliquot of the lysed whole blood which is transferred from the first cuvette to the second cuvette for the Hb measurement is also used for the measurement of HbA1c. The second cuvette contains an anti-HbA1c antibody in a buffered reagent. Hemoglobin A1c in the sample reacts with anti-HbA1c antibody to form a soluble antigen-antibody complex. A polyhapten reagent containing multiple HbA1c epitopes is then added to this cuvette. The polyhapten reacts with excess (free) anti-HbA1c antibodies to form an insoluble antibody-polyhapten complex. The rate of this reaction is measured turbidimetrically at 340 nm and blanked at 700 nm and is inversely proportional to the concentration of HbA1c in the sample.

hemoglobin A1c + anti-HbA1c antibody → hemoglobin A1c -anti-HbA1c antibody complex

anti-HbA1c antibody (excess) + polyhapten → Ab / polyhapten complex (absorbs at 340 nm)

Intended Use:
The HA1C assay on the Dimension® clinical chemistry system is an *in vitro* diagnostic assay for the quantitative determination of percent hemoglobin A1c (HbA1c) in anticoagulated whole blood. Measurements of percent hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

Comparison to Predicate Device:

Item	[redacted]	[redacted]
Operating Principle	turbidimetric inhibition immunoassay (TINIA)	turbidimetric inhibition immunoassay (TINIA)
Detection	Hb - Colorimetric at 405 nm and 700nm HbA1c – turbidimetric at 340 nm blanked at 700 nm	Hb - Colorimetric at 660 nm and 570 HbA1c – turbidimetric at 340 nm blanked at 700 nm
Specimen Type	anticoagulated whole blood	anticoagulated whole blood
Sample Pre-treatment	none required	required

* Tina-quant is a registered trademark of Roche Diagnostics Corporation

Comments on Substantial Equivalence:
Method correlation between the Roche Tina-quant® HBA1C II on Hitachi and Dimension® HA1C methods was evaluated with 136 anticoagulated whole blood samples ranging from 4.9% to 16.7% HbA1c. These samples provided a correlation coefficient of 0.994, a slope of 0.985, and an intercept of 0.3% HbA1c.

Conclusion:
The HA1C assay on the Dimension® clinical chemistry system is substantially equivalent in principle and performance to the Roche Tina-quant® HBA1C II based on the split sample comparison summarized in the previous section, Comments on Substantial Equivalence.

Cathy P. Craft
Director, Regulatory Affairs
Date: June 8, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 5 2001

Ms. Cathy P. Craft
Director, Regulatory Affairs
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k011852
Trade/Device Name: Dimension® HAIC Assay
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: August 30, 2001
Received: August 31, 2001

Dear Ms. Craft:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications For Use Statement

Device Name: Dimension® HA1C Assay

Indications for Use:
The HA1C assay used on the Dimension® clinical chemistry system is an *in vitro* diagnostic assay for the quantitative determination of percent hemoglobin A1c (HbA1c) in anticoagulated whole blood. Measurements of percent hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

Cathy P. Craft
Director, Regulatory Affairs
June 8, 2001

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011852/S1

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)